



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0324; FRL-9349-6]

Flutriafol; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of flutriafol in or on cotton, undelinted seed; cotton, meal; cotton, refined oil; and cotton gin byproducts. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cotton. This regulation establishes a maximum permissible level for residues of flutriafol in or on cotton commodities. The time-limited tolerances expire on December 31, 2014.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0324, is available either electronically through <http://www.regulations.gov> or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open

from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Debra Rate, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 306-0309; email address: rate.debra@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0324 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0324, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for combined residues of flutriafol, its metabolites and degradates, in or on cotton, undelinted seed at 0.35 parts per million (ppm); cotton, meal at 0.5 ppm; cotton, refined oil at 0.5 ppm; and cotton gin byproducts at 0.50 ppm. These time-limited tolerances expire on December 31, 2014.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Flutriafol on Cotton and FFDCA Tolerances

This is the first section 18 request received for the use of flutriafol on cotton. Texas had the worst one-year, 2011, drought since 1895 (Huber, 2011). Under the drought conditions cotton root rot fungus flourished on stressed cotton plants to reduce yields and produce more fungal inoculums that will remain viable for 5-8 years in the soil. The submitted information showed that in 2011, cotton growers suffered 30-66 percent yield losses in fields infested with cotton root rot. Fields infested with cotton root

rot disease last year are expected to have even heavier losses this year unless the pest is effectively mitigated.

In Texas, approximately 12% of 2.4 million acres of cotton are infested with the root rot fungus. In 2012, yield losses are expected to be like 2011 or higher without the use of flutriafol. The severe drought condition of 2011 was a non-routine event that stressed cotton plants. The drought stressed cotton is more susceptible to the root rot fungus which causes high yield losses and build-up of fungal inoculums in soil. The drought condition and elevated pest pressure are likely to continue to cause severe yield losses in the 2012 growing season resulting in significant economic losses.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of flutriafol on cotton for control of cotton root rot, caused by the fungus *Phymatotrichum omnivorum* in Texas.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of flutriafol in or on cotton. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without advance notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2014, under FFDCA

section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cotton, undelinted seed; cotton, meal; cotton, refined oil and cotton, gin byproducts after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether flutriafol meets FIFRA's registration requirements for use on cotton or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of flutriafol by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves serve as the authority for persons in any State other than Texas to use this pesticide on cotton absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for flutriafol, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of

section 408 of the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerances for combined residues of flutriafol, its metabolites and degradates, in or on cotton, undelinted seed at 0.35 ppm; cotton, meal at 0.5 ppm; cotton, refined oil at 0.5 ppm and cotton, gin byproducts at 0.5 ppm.

On November 9, 2011, the Agency published a final rule (76 FR 69643) (FRL-9325-6) establishing tolerances for residues of flutriafol, ((±)-[alpha]-(2-fluorophenyl)-[alpha]-(4-fluorophenyl)-1H-1,2,4-triazole-1-ethanol, in or on multiple commodities. Since the publication of that final rule, the Agency has conducted risk assessments evaluating the use of flutriafol on cotton under section 18 of FIFRA. These new risk assessments have not identified any changes to the hazard data, hazard characterization or end-points relied upon in the November 9, 2011, tolerance rule. The additional exposures and risks associated with residues resulting from the section 18 use on cotton are negligible and do not significantly change the previous acute and chronic aggregate risk. Therefore, establishing the time-limited tolerances on the cotton commodities will not change the most recent aggregate risks resulting from the use of flutriafol, as discussed in the November 9, 2011 **Federal Register**. Refer to the November 9, 2011 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety.

Based on the risk assessments and findings discussed in the final rule published in the **Federal Register** of November 9, 2011, as well as recent documents in the current docket, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children, from aggregate exposure to flutriafol residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (gas chromatography/Nitrogen/Phosphorus detector (NPD) for tolerances and method ICIA AM00306 for ruminant liver) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex, Canada, and Mexico have not established MRLs for flutriafol in or on cotton commodities.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of flutriafol, [(±)-α-(2-fluorophenyl)-α-(4-fluorophenyl)-1 H -1,2,4-triazole-1-ethanol], including its metabolites and degradates, in or on cotton, undelinted seed at 0.35 ppm; cotton, meal at 0.5 ppm; cotton, refined oil at 0.5 ppm; and cotton, gin byproducts at 0.5 ppm. These tolerances expire on December 31, 2014.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal

Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National

Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 3, 2012.

Lois Rossi,

Director, Registration Division. Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.629 is amended by revising paragraph (b) to read as follows:

§ 180.629 Flutriafol; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of flutriafol, [(±)-α-(2-fluorophenyl)-α-(4-fluorophenyl)-1 H -1,2,4-triazole-1-ethanol], including its metabolites and degradates in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Cotton, gin byproducts	0.5	12/31/14
Cotton, meal	0.5	12/31/14
Cotton, refined oil	0.5	12/31/14
Cotton, undelinted seed	0.35	12/31/14

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